

a therapeutic substance having a greater degree of solubility in the second polymer than the first polymer such that all of or a significant amount of the therapeutic substance is distributed in the second polymer but not the first polymer.

45. (New) The system of claim 44, wherein the second polymer has a glass transition temperature less than 37° C.

46. (New) The system of claim 44, wherein the second polymer constitutes less than about 30% by volume of the total volume of the first polymer plus the second polymer.

47. (New) The system of claim 44, wherein the second polymer constitutes more than about 30% by volume of the total volume of the first polymer plus the second polymer.

REMARKS

Claims 1-13, 16, 17, and 44-47 are pending in this application. Claims 18-43 have been canceled as non-elected claims following a restriction requirement. Claims 14 and 15 have been canceled in this response. The numbered paragraphs below correspond to the Examiner's numbered paragraphs.

1./2. Applicant affirms election of Group I, Claims 1-17.

3. Claims 2 and 3 stand rejected under 35 U.S.C. § 112, second paragraph. Claims 2 and 3 have been amended to cure the rejection. Withdrawal of the rejection is respectfully requested.

4. Claims 1, 2, 4, 5, 10, 11 and 17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Eury et al. (U.S. Patent No. 5,605,696). Eury et al. teach "a polymeric material containing a therapeutically effective amount of a therapeutic drug that can be combined with the reinforcement structure of an intravascular stent..." (col. 3, lines 15-18). "[A] selected therapeutic drug is preferably intimately mixed with the selected polymeric material so as to uniformly disperse the therapeutic drug in the

polymeric material” (col. 3, lines 26-29). Eury et al. further disclose the addition of a prosigen into the drug loaded polymer for forming a porous membrane (col. 4, lines 60-63 and col. 5, lines 1-9). Nowhere do Eury et al. disclose “**a drug incorporated into the drug-enriched phase, the drug having preferential solubility for the polymeric drug-enriched phase than the bulk polymer phase wherein the bulk polymeric phase is substantially or completely devoid of the drug,**” as recited by Claim 1. Accordingly, Claim 1 is patentably allowable over Eury et al. Claims 2, 4, 5, 10, 11 and 17 depend directly from Claim 1 and are therefore patentably allowable for at least the same reason. Withdrawal of the rejection and allowance of the claims is respectfully requested.

5. Claims 1-17 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Hossainy et al. (U.S. Patent No. 6,153,252). As correctly indicated by the Examiner, Hossainy et al. do disclose using polymer blends “to control the release rate of different agents or to provide desirable balance of coating” (col. 7, lines 29, 30). However, Hossainy et al. fail to teach “a bulk polymer phase; a polymeric drug-enriched phase within the bulk polymer phase, **the polymeric drug-enriched phase being substantially or completely insoluble in the bulk polymer phase; and a drug incorporated into the drug-enriched phase, the drug having preferential solubility for the polymeric drug-enriched phase than the bulk polymer phase wherein the bulk polymeric phase is substantially or completely devoid of the drug,**” as recited by Claim 1. Accordingly, Claim 1 is patentably allowable over Hossainy et al. Claims 2-13, 16 and 17 depend directly and indirectly from Claim 1 and are allowable for at least the same reason. Claims 14 and 15 have been canceled. Withdrawal of the rejection and allowance of the claims is respectfully requested.

CONCLUSION


Claims 1-13, 16, 17 and 44-47 are pending in this application.

Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0323.

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Version With Markings To Show Changes Made

In the Claims:

1. (Amended) A drug release system comprising:

a bulk polymer phase;

a polymeric drug-enriched phase within the bulk polymer phase, the
polymeric drug-enriched phase being substantially or completely insoluble in the
bulk polymer phase; and

[at least one] a drug incorporated into the drug-enriched phase, the drug
having preferential solubility for the polymeric drug-enriched phase than the bulk
polymer phase wherein the bulk polymeric phase is substantially or completely
devoid of the drug.
2. (Amended) The drug release system of claim 1 wherein the drug-enriched
phase comprises [discrete, discontinuous] sites within the bulk polymer phase that are not
interconnecting.
3. (Amended) The drug release system of claim 1 wherein the drug-enriched
phase comprises sites within the bulk phase that are [discrete] intermittent in cross-
section [but] and continuous in a longitudinal direction.
13. (Amended) The drug release system of claim [9] 1 wherein the drug
enriched phase [reacts with the vinyl ether groups of the bulk phase to form] is
conjugated to the bulk polymer phase via a urethane linkage.

Please cancel claims 14 and 15.

Claims 18-43 have been canceled.

Please add the following new claims:

- 44. A drug release system for a stent, comprising:

a first polymer;

a second polymer combined with the first polymer, the second polymer being significantly insoluble in the first polymer; and

a therapeutic substance having a greater degree of solubility in the second polymer than the first polymer such that all of or a significant amount of the therapeutic substance is distributed in the second polymer but not the first polymer.

45. The system of claim 44, wherein the second polymer has a glass transition temperature that is less than 37° C.

46. The system of claim 44, wherein the second polymer constitutes less than about 30% by volume of the total volume of the first polymer plus the second polymer.

47. The system of claim 44, wherein the second polymer constitutes more than about 30% by volume of the total volume of the first polymer plus the second polymer.--